hallmark characteristics of an addictive drug. Moreover, through the Council for Tobacco Research, the cigarette manufacturers funded research that reported that "smoking is a form of dependence no less binding than that of other addictive drugs."

Fourth, the evidence shows that the manufacturers know that consumers smoke cigarettes primarily to obtain the pharmacological effects of nicotine. This point is repeatedly acknowledged in internal company documents. For example, researchers for Philip Morris have stated that nicotine is "the primary reason why people smoke" and that nicotine is "the physiologically active component of smoke having the greatest consequence to the consumer"; researchers for RJR have stated that "the confirmed user of tobacco is primarily seeking the physiological 'satisfaction' derived from nicotine" and that "[w]ithout any question, the desire to smoke is based upon the effect of nicotine on the body"; and BATCO's director of research has stated that "[t]he tobacco smoking habit is reinforced or dependent upon the psycho-pharmacological effects mainly of nicotine." This knowledge of the central role of nicotine in cigarette smoking was communicated to the highest levels of the companies. In 1969, for instance, Philip Morris' vice president for research and development told the Philip Morris board of directors that "the ultimate explanation for the perpetuated cigarette habit resides in the pharmacological effect of smoke upon the body of the smoker."

Fifth, the evidence shows that in their internal documents, the cigarette manufacturers expressly refer to cigarettes as devices for the delivery of nicotine. For instance, researchers for Philip Morris have described cigarettes as a "dispenser for a dose unit of nicotine" and as a "nicotine delivery device"; a senior researcher for RJR has

described cigarettes as a "vehicle for delivering nicotine"; and researchers for BATCO have described cigarettes as the "means of providing nicotine dose in a metered fashion" and as a device that provides the smoker "very flexible control over titrating his desired dose of nicotine."

This evidence establishes that cigarettes are intended by the manufacturers to affect the structure and function of the body. It demonstrates that the manufacturers know that nicotine is pharmacologically active; that consumers smoke primarily to obtain the pharmacological effects of nicotine; and that cigarettes function as devices for the delivery of nicotine. The evidence thus shows that when the manufacturers offer cigarettes for sale, they "have in mind" that their products will be used for the particular purpose of affecting the structure and function of the body.

In addition to the evidence showing that cigarette manufacturers "have in mind" the use of cigarettes for pharmacological purposes, the record shows that the manufacturers "design" cigarettes to ensure the delivery of a pharmacologically active dose of nicotine to the smoker. The evidence in the record shows that the manufacturers have conducted extensive product research and development to find ways to maintain adequate nicotine levels in low-tar cigarettes. According to one former senior official at Philip Morris, "a key objective of the cigarette industry over the last 20-30 years" was "maintaining an acceptable and pharmacologically active nicotine level" in low-tar cigarettes. Internal industry documents in the record disclose research to determine the dose of nicotine that must be delivered to provide "pharmacological satisfaction" to the

smoker, as well as estimates by industry scientists of the minimum and optimum doses of nicotine that cigarettes must deliver.

Among the many examples in the record of product research and development to enhance relative nicotine deliveries, Philip Morris conducted extensive research to identify "the optimal nicotine/tar ratios for cigarette acceptability of relatively low-delivery cigarettes"; RJR developed alternative tobacco products that provide a "more efficient and direct way to provide the desired nicotine dosage than the present system involving combustion of tobacco"; and Brown & Williamson investigated chemical manipulation to raise smoke pH, thereby increasing "free" nicotine delivery, and used genetic engineering to breed a high-nicotine tobacco plant called Y-1.

The record before the Agency shows that several methods of enhancing nicotine deliveries are used in the manufacture of commercial cigarettes. Tobacco blending to raise the nicotine concentration in low-tar cigarettes is common. As the vice chairman and chief operating officer of Lorillard Tobacco Co. has stated, "the lowest tar segment is composed of cigarettes utilizing a tobacco blend which is significantly higher in nicotine." Another common technique for enhancing nicotine deliveries in low-tar cigarettes is the use of filter and ventilation systems that by design remove a higher percentage of tar than nicotine. Yet a third type of nicotine manipulation is the addition of ammonia compounds that increase the delivery of "free" nicotine to smokers by raising the alkalinity or pH of tobacco smoke. These ammonia technologies are widely used within the industry.

The record establishes that an important reason why the manufacturers design cigarettes that provide pharmacologically active doses of nicotine is to satisfy the demands

of users. The manufacturers concede in their comments that their "intent is to design, manufacture and market . . . cigarettes to meet the preferences of adult smokers." The preferences of most smokers, however, include obtaining sufficient nicotine to sustain their addiction and to experience nicotine's mood-altering effects. What the cigarette manufacturers describe as producing cigarettes that satisfy consumer preferences is, in reality, producing cigarettes that provide the pharmacological effects of nicotine sought by consumers. The effect of maintaining a pharmacologically active dose of nicotine in cigarettes is to keep consumers smoking by sustaining their addiction.

The evidence that the manufacturers "design" cigarettes to provide a pharmacologically active dose of nicotine is further proof that the manufacturers intend cigarettes to affect the structure and function of the body. Taken together, the evidence shows that the cigarette manufacturers: (1) "have in mind" the use of cigarettes for the particular purpose of delivering the pharmacological effects of nicotine, and (2) "design" their products to provide these effects. This evidence convincingly demonstrates that the pharmacological effects of cigarettes are "intended" by the manufacturers.

D. The Statements, Research, and Actions of the Smokeless Tobacco Manufacturers Show that the Manufacturers Intend their Products to Affect the Structure and Function of the Body

The administrative record also contains evidence of the statements, research, and actions of the smokeless tobacco manufacturers. Like the evidence of the statements, research, and actions of the cigarette manufacturers, this evidence establishes that the smokeless tobacco manufacturers intend to affect the structure and function of the body.

First, the evidence in the record shows that the smokeless tobacco manufacturers know that nicotine is a pharmacologically active drug and that consumers use smokeless tobacco to obtain the pharmacological effects of nicotine. As a senior vice president for United States Tobacco Co. (UST) stated, "virtually all tobacco usage is based upon nicotine, 'the kick,' satisfaction." Researchers affiliated with Brown & Williamson acknowledge that "nicotine . . . absorbed through . . . the lining of the nose or mouth . . . will quickly enter a direct route, in the blood, to the brain."

Second, the evidence shows that the smokeless tobacco manufacturers manipulate the nicotine delivery of their products in a manner that promotes tolerance and addiction to nicotine. This manipulation is accomplished through the use of chemicals that alter the pH of the smokeless tobacco. Moist snuff brands that are marketed as "starter" brands have a low pH and consequently deliver a low level of "free" nicotine to the user, limiting the absorption of nicotine in the mouth. The low nicotine deliveries allow the new user to develop a tolerance to nicotine without experiencing adverse reactions such as nausea and vomiting. In contrast, moist snuff brands that are marketed to experienced users have a high pH and consequently deliver a high level of "free" nicotine to the user, increasing the amount of nicotine available for absorption. The increased nicotine deliveries provide sufficient nicotine to sustain the user's addiction.

Third, the evidence shows that smokeless tobacco use and addiction to nicotine has substantially increased among teenagers since the manufacturers began to manipulate nicotine deliveries. Before the introduction of starter brands with low levels of nicotine delivery, virtually no teenagers and young adults used smokeless tobacco. After the

smokeless tobacco manufacturers began to market low-nicotine "starter" brands in the 1970's, however, use of smokeless tobacco by teenagers rose dramatically. Use of smokeless tobacco by adolescent males aged 18 to 19, for instance, increased almost 1,500% between 1971 and 1991. Most of the regular teenage users of smokeless tobacco graduate to higher nicotine brands. An analysis by the Centers for Disease Control and Prevention found that the pattern of smokeless tobacco use by teenagers "support[s] the hypothesis that snuff users in earlier stages of tobacco use and nicotine addiction use brands with low levels of free nicotine and then 'graduate' to brands with high levels."

This evidence of: (1) knowledge of nicotine pharmacology, (2) manipulation of nicotine deliveries, and (3) graduation to higher nicotine brands among young users is a sufficient basis to establish that the smokeless tobacco manufacturers intend to affect the structure and function of the body.

In addition to this industry-wide evidence of intended use, the record contains numerous documents from the nation's largest smokeless tobacco manufacturer, UST. The UST documents in the record show that:

- UST officials in the early 1970's recommended the development of products with "three different . . . strengths of nicotine[:] . . . a. High nicotine, strong tobacco flavor . . . b. Medium strength of nicotine . . . c. Low nicotine, sweet product." In particular, UST officials recommended the development of a product that provided "mild" nicotine satisfaction targeted at "new users . . . age group 15-35."

- Shortly after these recommendations, UST began aggressively to market low-nicotine products, targeted "for you guys just starting out." Marketing techniques included free sampling on college campuses and at sports events. Advertisements included instructions on use for new users.

- Numerous UST documents and statements refer to an explicit "graduation process" in which users of smokeless tobacco are encouraged to start with low-nicotine starter brands and then progress to higher nicotine brands. For

instance, a UST vice president has stated that Skoal Bandits, one of UST's low-nicotine brands, "is the introductory product, and we look towards establishing a normal graduation process."

These UST documents confirm that smokeless tobacco manufacturers deliberately produce brands with a range of nicotine deliveries in order to allow users to progress (or "graduate") from low-delivery products to high-delivery products. They thus corroborate the Agency's finding that smokeless tobacco is intended to affect the structure and function of the body.

E. The "Intended Use" of a Product Is Not Determined Only on the Basis of Promotional Claims

The principal legal argument of the tobacco industry is that the intended use of a product must be determined exclusively on the basis of the promotional claims made by the manufacturer. Under the industry's legal theory, the Agency must disregard the voluminous internal tobacco industry documents showing that the manufacturers have in mind, and design their products to provide, the pharmacological effects of nicotine. The tobacco industry also urges the Agency to disregard the evidence of the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco, as well as the evidence of the actual consumer use of these products for pharmacological purposes.

The Agency rejects the industry's legal argument. First, the industry's position is contrary to the plain language of the Act. The Act does not say that only products "promoted" to affect the structure or function of the body are drugs or devices. Rather, the Act says that products "intended" to affect the structure or function of the body are drugs or devices. The plain meaning of "intend" is significantly broader than the meaning of "promote." As summarized above, the plain meaning of "intend" includes "to have in

mind" and "to design" for a particular use. The evidence that is relevant to determining the uses that a manufacturer "has in mind" or "designs" includes not just the promotional claims of the manufacturer, but also the internal statements of the manufacturer, as well as the manufacturer's research and actions. Moreover, the ordinary meaning of "intend" also encompasses the reasonably foreseeable consequences of the manufacturer's actions, thereby making consideration of the foreseeable pharmacological effects and uses of a product relevant to its intended use.

Second, the industry's position is contrary to FDA's regulations. These regulations provide that the term "intended use" refers to the "objective intent" of the manufacturer. Under these regulations, the Agency determines the intent of the manufacturer objectively by evaluating all of the relevant evidence in the record from the perspective of a reasonable fact-finder. FDA's regulations expressly direct the Agency to consider the manufacturer's "knowledge" of the use of the product; the manufacturer's "expressions" and "oral or written statements"; and the "circumstances surrounding the distribution of the article." 21 CFR 201.128, 801.4. Thus, the regulations expressly provide that the Agency should consider a broad range of evidence in determining intended use, not merely the manufacturer's promotional claims.

Third, the industry's position is contrary to judicial decisions interpreting the Act. These decisions have applied the Act's definitions of drug and device to two different types of products. The first type of product is one that contains no known drug ingredients and has no known pharmacological effects or uses. In cases involving such products, the courts recognize that a manufacturer's promotional claims have a crucial

role in establishing intended use. Even a product like mineral water can be brought within FDA's jurisdiction by advertisements that make pharmacological claims. *See Bradley v. United States*, 264 F. 79 (5th Cir. 1920).

The situation is fundamentally different, however, when the product contains a known drug ingredient like nicotine that has known pharmacological effects and uses. When a product is pharmacologically active, the courts have recognized that "a fact finder should be free to pierce . . . a manufacturer's misleading . . . labels to find actual therapeutic intent on the basis of objective evidence." *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 789 (2d Cir. 1974). Thus, contrary to the industry's contention, the courts have recognized that in determining intended use, FDA may consider a wide range of evidence beyond the manufacturer's promotional claims, including evidence of the pharmacological effects of the product, *e.g., United States v. Undetermined Quantities . . . "Pets Smellfree,"* 22 F.3d 235, 240 (10th Cir. 1994); the purposes for which consumers actually use the product, *e.g., ASH*, 655 F.2d at 239-240; the medical use of the product, *e.g., United States v. An Article of Device . . . Toftness Radiation Detector*, 731 F.2d 1253, 1257 (7th Cir. 1984); and how the product was formulated, *e.g., American Health Products Co. v. Hayes*, 574 F. Supp. 1498, 1508 (S.D.N.Y. 1983).

Fourth, the industry's position is contrary to FDA's administrative precedent. In a broad range of instances, FDA has asserted jurisdiction over products based on the likely pharmacological effects and uses of the product—not express promotional claims. Indeed, in many of these instances, the manufacturer's promotional claims were designed to disguise the actual intended use of the product.

Fifth, the industry's position is contrary to the public health objectives of the Act. If promotional claims alone determined the intended use of a product, virtually any manufacturer of drugs or devices could avoid the Act's reach by simply refraining from making pharmacological claims for the product. For instance, under the industry's interpretation, a company could market a potent tranquilizer or amphetamine for its "pleasurable" effect and escape FDA regulation. To protect the public from the unregulated distribution of products with pharmacologically active ingredients, the Agency must be able to look beyond a manufacturer's promotional claims when determining whether to regulate such products.

For these reasons, the Agency rejects the tobacco industry's legal theory that intended use is determined exclusively on the basis of promotional claims. The Agency also rejects the premise of the industry's position—namely, that their promotional claims demonstrate that cigarettes and smokeless tobacco are not intended to affect the structure and function of the body. To the contrary, as internal tobacco company documents indicate, promises of "satisfaction" in tobacco advertisements imply that cigarettes and smokeless tobacco will provide consumers with desired pharmacological effects of nicotine. These implied drug claims lend support to the Agency's finding that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

F. Response to Additional Comments

This section responds to additional comments regarding the evidence of the intended use of cigarettes and smokeless tobacco and the Agency's use of this evidence.